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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,243	09/15/2003	Pier Giovanni Baraldi	PAT-0032-US-CNT	2867

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KING PHARMACEUTICALS, INC.
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,243

Applicant(s)

BARALDI, PIER GIOVANNI

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input checked="" type="checkbox"/> Other: <u>East Search</u> . |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group 1: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is formula (IA) with a bicyclic core of **4,7-dihydro-5H-thieno[2,3-c]thiopyran-3-yl**, classified in classes 514 and 549, various subclasses depending on substituents.
- Group 2: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is formula (IA) with a bicyclic core of **4,5-dihydro-thieno[2,3-b]thiophen-3-yl**, classified in classes 514 and 549, various subclasses depending on substituents.
- Group 3: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is formula (IA) with a bicyclic core of **4,5,6,7-tetrahydrobenzo[b]thiophen-3-yl**, classified in classes 514 and 549, various subclasses depending on substituents.
- Group 4: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is formula (IA) with a bicyclic core of **5,6-dihydro-4H-cyclopenta[b]thiophen-3-yl**, classified in classes 514 and 549, various subclasses depending on substituents.
- Group 5: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is formula (IA) with a bicyclic core of **4,5,6,7-**

tetrahydrothieno[2,3-c]pyridin-3-yl, classified in classes 514 and 546, various subclasses depending on substituents.

- Group 6: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is formula (IA) with a bicyclic core of **4H-1,5,7-trithia-inden-3-yl**, classified in classes 514 and 544, various subclasses depending on substituents.
- Group 7: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is formula (IB) or a core of **4,5-dimethylthiophen-3-yl**, classified in classes 514 and 549, various subclasses depending on substituents.
- Group 8: Claims 1-11 (in part), drawn to a method of treating various diseases wherein the compound is one of the remaining compounds of formula (IA) with a bicyclic core not mentioned above, classified in classes 514, 540, 544, 546, 549, various subclasses depending on substituents.
- Group 9: Claims 12-15 (in part), drawn to a method for determining the compound's activity at moderating adenosine receptors wherein the compound is formula (IA) with a bicyclic core of **4,7-dihydro-5H-thieno[2,3-c]thiopyran-3-yl**, classified in classes 514 and 549, various subclasses depending on substituents.
- Group 10: Claims 12-15 (in part), drawn to a method for determining the compound's activity at moderating adenosine receptors wherein the compound is

formula (IA) with a bicyclic core of **4,5-dihydro-thieno[2,3-b]thiophen-3-yl**,
classified in classes 514 and 549, various subclasses depending on substituents.

Group 11: Claims 12-15 (in part), drawn to a method for determining the
compound's activity at moderating adenosine receptors wherein the compound is
formula (IA) with a bicyclic core of **4,5,6,7-tetrahydrobenzo[b]thiophen-3-yl**,
classified in classes 514 and 549, various subclasses depending on substituents.

Group 12: Claims 12-15 (in part), drawn to a method for determining the
compound's activity at moderating adenosine receptors wherein the compound is
formula (IA) with a bicyclic core of **5,6-dihydro-4H-cyclopenta[b]thiophen-3-yl**,
classified in classes 514 and 549, various subclasses depending on
substituents.

Group 13: Claims 12-15 (in part), drawn to a method for determining the
compound's activity at moderating adenosine receptors wherein the compound is
formula (IA) with a bicyclic core of **4,5,6,7-tetrahydrothieno[2,3-c]pyridin-3-yl**,
classified in classes 514 and 546, various subclasses depending on substituents.

Group 14: Claims 12-15 (in part), drawn to a method for determining the
compound's activity at moderating adenosine receptors wherein the compound is
formula (IA) with a bicyclic core of **4H-1,5,7-trithia-inden-3-yl**, classified in
classes 514 and 544, various subclasses depending on substituents.

Group 15: Claims 12-15 (in part), drawn to a method for determining the
compound's activity at moderating adenosine receptors wherein the compound is

formula (IB) or a core of **4,5-dimethylthiophen-3-yl**, classified in classes 514 and 549, various subclasses depending on substituents.

Group 16: Claims 12-15 (in part), drawn to a method for determining the compound's activity at moderating adenosine receptors wherein the compound is one of the remaining compounds of formula (IA) with a bicyclic core not mentioned above, classified in classes 514, 540, 544, 546, 549, various subclasses depending on substituents.

Inventions of Groups 1-16 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct from each other because they are drawn to two different processes using compounds of two different formulae, (IA) and (IB). Formula (IA) has various bicyclic core determined by ring atoms A, B and the value of "m" and "n". Formula (IB) is a substituted *dimethyl-thiophen* compound which does not have a common core with formula (IA).

The inventions of Groups 1-6, 8-14 and 16 are drawn to a method using a compound of formula (IA) which has a variable core determined by ring atoms A, B and the value of "m" and "n". Said core does not sufficiently define the invention, and it is not a contribution to the art. It is the combination of A, B and the value of "m" and "n" that gives compounds of each group their unique bicyclic core as well as physical, chemical properties and biological activities. Depending on what they represent, the claimed formula would have different structure. Clearly, the Markush group of formula (IA) is improper.

The inventions of Groups 7 and 15 are drawn to a method using a compound of formula (IB) which has a core of *dimethyl-thiophen*, and is entirely different from the bicyclic core of formula (IA).

Thus, a reference anticipated or rendered obvious compounds of one group would not do so to those of other groups. Therefore, a separate search is required for each group.

Therefore, the search and examination for all 16 groups would impose a serious burden on the examiner in charge of this invention. Note, a preliminary search in EAST yields a total of 1,233 hits which clearly shows an overwhelming number of references for consideration.

Due to the complexity nature of the grouping, the restriction is presented in writing. Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.


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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

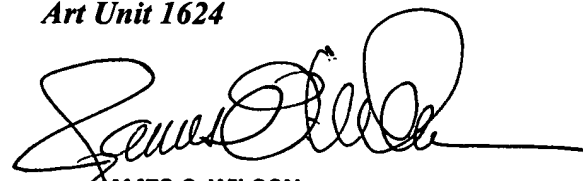
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Tamthom N. Truong
Examiner
Art Unit 1624

9-19-06


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